

Appointment

From: Osterweil, Elyse [Osterweil.Elyse@epa.gov]
Sent: 6/23/2021 5:37:39 PM
To: Osterweil, Elyse [Osterweil.Elyse@epa.gov]; Camacho, Iris [Camacho.Iris@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Salazar, Keith [Salazar.Keith@epa.gov]; Cox, James W. [cox.jamesw@epa.gov]; Childs, Elizabeth [childs.elizabeth@epa.gov]; Choi, Kyoungju [Choi.Kyoungju@epa.gov]; Nahar, Muna [Nahar.Muna@epa.gov]
CC: OCSPP ALL [OCSPP_ALL@epa.gov]; Lloyd, Matthew [Lloyd.Matthew@epa.gov]; Kraka, Ernest [Kraka.Ernest@epa.gov]; Swartz, Christina [Swartz.Christina@epa.gov]; Villanueva, Philip [Villanueva.Philip@epa.gov]; Smearman, Stephen [Smearman.Stephen@epa.gov]; Spatz, Dana [Spatz.Dana@epa.gov]; Maignan, Tawanda [Maignan.Tawanda@epa.gov]; Saunders, Kaitlin [Saunders.Kaitlin@epa.gov]; Uzoukwu, Chinyere [Uzoukwu.Chinyere@epa.gov]; Snyder, Charlotte [snyder.charlotte@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Sames, Jayna [Sames.Jayna@epa.gov]; Prieto, Rafael [Prieto.Rafael@epa.gov]; Breithaupt, James [Breithaupt.James@epa.gov]; Liccione, John [Liccione.John@epa.gov]; Lo, Edward [Lo.Edward@epa.gov]; Friedlander, Leslie [Friedlander.Leslie@epa.gov]; Antwi, Frank [antwi.frank@epa.gov]; Anapolle, Kent [Anapolle.Kent@epa.gov]; Adams, Melanie [Adams.Melanie@epa.gov]; Cooper, Harold [Cooper.Harold@epa.gov]; Hrdy, David [Hrdy.David@epa.gov]; Phillips, Martin B. [phillips.martinb@epa.gov]; Wheeler, Maya [Wheeler.Maya.B@epa.gov]; Fothergill, Kent [fothergill.kent@epa.gov]; White, Katrina [White.Katrina@epa.gov]; Yarros, Justin [Yarros.Justin@epa.gov]; Weiner, Janet [Weiner.Janet@epa.gov]; Mosby, Jackie [Mosby.Jackie@epa.gov]; Master, Barbora [Master.Barbora@epa.gov]; Irwin, William [Irwin.William@epa.gov]; Garzon Moreno, Andres [GarzonMoreno.Andres@epa.gov]; Hurst, Savannah [Hurst.Savannah@epa.gov]; Eckel, William [Eckel.William@epa.gov]; Hummel, Natalie [Hummel.Natalie@epa.gov]; Sleasman, Katherine [Sleasman.Katherine@epa.gov]; Knott, Steven [Knott.Steven@epa.gov]; Lang, Elizabeth [Lang.Elizabeth@epa.gov]; Gowda, Srinivas [Gowda.Srinivas@epa.gov]; Turley, Alexandra [Turley.Alexandra@epa.gov]; Lalley, Thomas [Lalley.Thomas@epa.gov]; Chang, Ning-Ying [Chang.Ning-Ying@epa.gov]; Liberatore, Samuel [Liberatore.Samuel@epa.gov]; Jing, Yin [Jing.Yin@epa.gov]; Britt, Adrian [Britt.Adrian@epa.gov]; McMahon, Tim [McMahon.Tim@epa.gov]; Kennedy, Amuel [Kennedy.Amuel@epa.gov]; Piper, Maya [Piper.Maya@epa.gov]; English, LisaRenee [English.LisaRenee@epa.gov]; Taylor, Christopher M. [Taylor.Christopher.M@epa.gov]; Harrington, Jamie [Harrington.Jamie@epa.gov]; Schechter, Kathryn [Schechter.Kathryn@epa.gov]; Lopez, Jose [Lopez.Jose@epa.gov]; Wright, Marisa [Wright.Marisa@epa.gov]; Nitzken, Anna [Nitzken.Anna@epa.gov]; bnames@berkeley.edu; Le, Madison [Le.Madison@epa.gov]; Freedhoff, Michal [Freedhoff.Michal@epa.gov]; Regan, Michael [Regan.Michael@epa.gov]; Harwood, Douglas (Ethan) [harwood.douglas@epa.gov]; Johnson, Hope [Johnson.Hope@epa.gov]; Biggio, Patricia [biggio.patricia@epa.gov]; Wait, Monica [Wait.Monica@epa.gov]; Taylor, Michele [Taylor.Michele@epa.gov]; Dandridge, Erin [dandridge.erin@epa.gov]; Muneer, Alie [muneer.alie@epa.gov]; Nguyen, Khue [Nguyen.Khue@epa.gov]; Browning, Cynthia [Browning.Cynthia@epa.gov]; Pates, John [Pates.John@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Barnett, Howard [Barnett.Howard@epa.gov]; Billingslea, Jesse [Billingslea.Jesse@epa.gov]; Mendez, Elizabeth [Mendez.Elizabeth@epa.gov]; Burris, Janet [burris.janet@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Murasaki, Seiichi [Murasaki.Seiichi@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Amati, Andrea [Amati.Andrea@epa.gov]; Nelsen, Ashley [Nelsen.Ashley@epa.gov]; Pinto, Ana [Pinto.Ana@epa.gov]; Thapa, Monica [Thapa.Monica@epa.gov]; Claude, Mary [Claude.Mary@epa.gov]; Scheltema, Christina [Scheltema.Christina@epa.gov]

Subject: FW: FISHBOWL INVITE to the New Chemicals Team Meeting

Start: 6/23/2021 7:00:00 PM

End: 6/23/2021 8:00:00 PM

Show Time As: Tentative

Required Attendees: Osterweil, Elyse; Camacho, Iris; Scarano, Louis; Salazar, Keith; Cox, James W.; Childs, Elizabeth; Choi, Kyoungju; Nahar, Muna

Optional Attendees: OCSPP ALL; Lloyd, Matthew; Kraka, Ernest; Swartz, Christina; Taylor, Michele; Villanueva, Philip; Dandridge, Erin; Smearman, Stephen; Spatz, Dana; Muneer, Alie; Maignan, Tawanda; Saunders, Kaitlin; Uzoukwu, Chinyere; Snyder, Charlotte; Edelstein, Rebecca; Sames, Jayna; Prieto, Rafael; Breithaupt, James; Liccione, John; Nguyen, Khue; Lo,

Edward; Friedlander, Leslie; Browning, Cynthia; Antwi, Frank; Anapolle, Kent; Adams, Melanie; Cooper, Harold; Pates, John; Hrady, David; Nesci, Kimberly; Barnett, Howard; Phillips, Martin B.; Wheeler, Maya; Billingslea, Jesse; Fothergill, Kent; White, Katrina; Yarros, Justin; Weiner, Janet; Mosby, Jackie; Master, Barbora; Irwin, William; Garzon Moreno, Andres; Mendez, Elizabeth; Burris, Janet; Hurst, Savannah; Eckel, William; Hummel, Natalie; Costello, Kevin; Sleasman, Katherine; Knott, Steven; Lang, Elizabeth; Gowda, Srinivas; Turley, Alexandra; Lalley, Thomas; Murasaki, Seiichi; Lowit, Anna; Chang, Ning-Ying; Liberatore, Samuel; Jing, Yin; Amati, Andrea; Britt, Adrian; McMahon, Tim; Kennedy, Amuel; Piper, Maya; English, LisaRenee; Taylor, Christopher M.; Harrington, Jamie; Nelsen, Ashley; Schechter, Kathryn; Lopez, Jose; Wright, Marisa; Pinto, Ana; Thapa, Monica; Claude, Mary; Nitzken, Anna; bnames@berkeley.edu; Le, Madison; Freedhoff, Michal; Regan, Michael; Scheltema, Christina; Harwood, Douglas (Ethan); Johnson, Hope; Biggio, Patricia; Wait, Monica

Dear Dr. Bruce Ames,

I am terribly sorry for the short notice, but I would like to cordially invite you to our EPA "fishbowl" meeting today at 3pm via MS Teams. The link to the meeting is below. The purpose of this invite is for transparency and allow the public to understand how we make science decisions under TSCA. One of the agenda items for our meeting today is related to your Ames assay that you developed and published in 1973. I thought you might be interested in learning how your assay was being used at the EPA. Dr. Iris Camacho, my supervisor, will be presenting information on why she believes that the Ames assay is sufficient to remove concerns about mutagenicity or cancer concerns for a chemical that is regulated under TSCA. I am uncertain to how long this practice has been taking place and for which chemicals. I tried to explain why this is not appropriate but I seem to have failed my supervisor's expectations, so I asked to Iris to present her perspective to the team and model how I should be presenting our scientific opinions to our human health hazard team for our new chemicals human health risk assessment (HHRAs) reports. It only came to my knowledge more recently this Fall 2020 that concerns for mutagenicity were being removed from our HHRAs based on the results from your Ames assay. I also asked her to present information on why she believes it is not appropriate to add a mutagenicity and cancer hazard concern for a chemical that has only 1 positive chromosomal aberration assay and data from a 28-day study to support hyperplasia in the GI tract.

Please be free to forward this invitation to anyone you who would like to join, listen in, and participate in this discussion. It would also be wonderful to hear your perspective on this since you are the original scientists who developed this assay that is so widely used today for regulatory purposes. See below for the invitation I sent to the OCSPP (Office of Chemical Safety and Pollution Prevention) at the EPA.

Thank for you for considering this invitation.
Be free to call or email me if you have any questions.

Thanks,
Elyse Osterweil

Elyse Lee Osterweil, Ph.D. (she/her)
Toxicologist
OCSPP/OPPT/NCD
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📠 (919)259-1438
✉ osterweil.elyse@epa.gov

-----Original Appointment-----

From: Osterweil, Elyse

Sent: Wednesday, June 23, 2021 12:07 PM

To: Osterweil, Elyse; Camacho, Iris; Scarano, Louis; Salazar, Keith; Cox, James W.; Childs, Elizabeth; Choi, Kyoungju; Nahar, Muna

Cc: OCSPP ALL; Lloyd, Matthew; Kraka, Ernest; Swartz, Christina; Taylor, Michele; Villanueva, Philip; Dandridge, Erin; Smearman, Stephen; Spatz, Dana; Muneer, Alie; Maignan, Tawanda; Saunders, Kaitlin; Uzoukwu, Chinyere; Snyder,

Charlotte; Edelstein, Rebecca; Sames, Jayna; Prieto, Rafael; Breithaupt, James; Liccione, John; Nguyen, Khue; Lo, Edward; Friedlander, Leslie; Browning, Cynthia; Antwi, Frank; Anapolle, Kent; Adams, Melanie; Cooper, Harold; Pates, John; Hrdy, David; Nesci, Kimberly; Barnett, Howard; Phillips, Martin B.; Wheeler, Maya; Billingslea, Jesse; Fothergill, Kent; White, Katrina; Yarros, Justin; Weiner, Janet; Mosby, Jackie; Master, Barbora; Irwin, William; Garzon Moreno, Andres; Mendez, Elizabeth; Burris, Janet; Hurst, Savannah; Eckel, William; Hummel, Natalie; Costello, Kevin; Sleasman, Katherine; Knott, Steven; Lang, Elizabeth; Gowda, Srinivas; Turley, Alexandra; Lalley, Thomas; Murasaki, Seiichi; Lowit, Anna

Subject: FISHBOWL INVITE to the New Chemicals Team Meeting

When: Wednesday, June 23, 2021 3:00 PM-4:00 PM (UTC-05:00) Indiana (East).

Where:

Dear All,

In response to the EPA MassMailer you received on April 12th 2021, I am cordially inviting you to participate in today's New Chemicals Team Meeting at 3pm, in a "fishbowl" format. My apologies for the late notice. Also, please be free to invite anyone from the public who may be interested in this first of many "fishbowls" in an effort to aid transparency, engage you and the public in assisting our decision-making process, and restore public trust. Please join us to witness how human health assessors make science recommendations and how management decisions are made new chemical substances in TSCA. The New Chemicals Team meeting is a meeting of human health assessors from the New Chemicals Division (NCD) in the Office of Pollution Prevention and Toxics (OPPT) in OCSPP, which operates under the Toxic Substances Control Act (TSCA) Section 5. There are currently 5 human health assessors in the division that conduct the hazard assessments for our risk assessments, me included. Due to the TSCA CBI restrictions and current Agency policy, we are one of the least transparent parts of the Agency. My sincere hope is that you will accept this invitation in an effort to be more transparent and ensure that we are using the best possible science available to make our decisions for some of the most toxic chemicals in the world. One wonderful outcome of this pandemic, is that we finally have the tools and technology available to make this possible and without presenting an undue burden to our regulatory duties. I ask that you not speak during the presentation and keep your mics muted until the end for questions and comments. You are also welcome to post in the chat box during the meeting. Any comments, questions, scientific opinions, etc are very welcome. For scientific opinions, it would be most helpful if you provide the references to support your perspective.

At this morning's NCD Human Health Disposition meeting today, I presented information to support why the Agency should retain mutagenicity and cancer hazard concerns for one of our incoming new chemical substances. Due to TSCA CBI, I am not able to share specific details about the chemical but I would like to invite you to listen in our meeting today. Iris Camacho, a Branch Chief and first-line decision maker in NCD for the human health risk assessment reports will be the presenter today. I requested this presentation be appropriate for a non-CBI audience

Brief Proposed Agenda:





- 1) Reasons why it is acceptable to remove a mutagenicity and cancer hazard concern based on 1 Ames assay.
- 2) Reasons why it is appropriate to conduct an oral to inhalation extrapolation for chemical that has portal of entry effects via eye/skin/respiratory tract and point of contact effects in the stomach.
- 3) Reasons why it is not appropriate to add a mutagenicity and cancer hazard concern for a chemical that has 1 positive chromosomal aberration assay and data from a 28-day study to support hyperplasia in the GI tract. Note the 28 day study is the longest duration study we have for one component of this TSCA chemical. There is no data on the new chemical substance.

If you are unable to attend, we will also be recording the meeting for later viewing.

Please let me know if you would like to continue receiving these invites to our "fishbowl".

Also, please be free to submit any comments or scientific opinions you have to me, Iris Camacho my supervisor, and/or our NCD team.

Elyse Lee Osterweil, Ph.D. (she/her)
Toxicologist
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